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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,035	02/09/2001	Tariq Ghayer	BBI-149	8433

959 7590 12/18/2001

LAHIVE & COCKFIELD  
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BOSTON, MA 02109

EXAMINER

JAMROZ, MARGARET E

ART UNIT PAPER NUMBER

1644

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/780,035	GHAYER ET AL.	
	Examiner	Art Unit	
	Margaret E Jamroz	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)         |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>restriction election facsimile</i> |

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### DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Technology Center 1600.

### ***Restriction Requirement***

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-2, drawn to a small molecule capable of binding a human IL-18; Class 530, subclass 500.

II. Claims 1-2, drawn to a peptide capable of binding a human IL-18; classified in Class 530, subclass 300.

III. Claims 1-2, drawn to a polypeptide capable of binding a human IL-18; classified in Class 530, subclasses 350.

IV. Claims 1-38 and 44-46, drawn to antibodies or fragments thereof capable of binding a human IL-18 and a composition; classified in Class 530, subclasses 387.3, 388.22, and 389.1; and Class 424, subclasses 133.1 and 145.1.

V. Claims 39-43, drawn to an isolated nucleic acid, a vector, a host cell, and a method of making an antibody by the host cell; classified in Class 536, subclass 23.1; and Class 435, subclasses 320.1, 325 and 69.1, respectively.

VI. Claims 47 and 49, drawn to a method for making an antibody by exposing an antibody repertoire to an antigen; classified in Class 435, subclass 7.1.

VII. Claim 47-50, drawn to a method for making an antibody by immunizing an animal with the antigen comprising an epitope of human IL-18; classified in Class 424, subclass 184.1.

VIII. Claims 47, 49, and 51-52, drawn to a method for making an antibody wherein the antibody repertoire is a recombinant antibody library and the method comprises screening the library with an antigen comprising an epitope of human IL-18; classified in Class 435, subclass 69.1.

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IX. Claims 53, 55, 57, and 59, drawn to a method for inhibiting human IL-18 activity with a small molecule; classified in Class 424, subclass 600.

X. Claims 53, 55, 57, and 59, drawn to a method for inhibiting human IL-18 activity with a peptide; classified in Class 514, subclass 12.

XI. Claims 53, 55, 57, and 59, drawn to a method for inhibiting human IL-18 activity with a polypeptide; classified in Class 514, subclass 12.

XII. Claims 53-60, drawn to a method for inhibiting human IL-18 activity with an antibody; classified in Class 424, subclasses 133.1, 135.1, and 143.1.

4. Groups I-V are different products. Compounds and nucleic acids differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

Groups I-V recite compounds which can be small molecules, peptides, polypeptides, antibodies, fragments thereof, and nucleic acids. Small molecules, peptides, polypeptides, antibodies, antibody fragments, and nucleic acids differ with respect to their structure, one of ordinary skill in the art would not envision one in view of the other. Therefore, the restriction has been set forth irrespective of the format of the claims.

5. Groups IV and VI-VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case, the product as claimed can be made by materially different processes, such as the three different processes in Groups VI-VIII.

6. Groups VI-XII are different methods. The inventions as grouped in Groups VI-XII are distinct, each from the other, because they represent different inventive endeavors as one does not suggest the other; therefore, each method is patentably distinct.

7. (Groups I and IX), (Groups II and X), (Groups III and XI), and (Groups IV and XII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the products of groups I-III can be used in a materially different process, such as immunogens, in addition to the methods inhibiting recited.

In the instant case, the products of group IV can be used in a materially different process, such as affinity purification, in addition to the methods inhibiting recited.

8. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

### ***Species Election***

9. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If Group IV is elected, applicant is required to elect a specific type of antibody (e.g. monoclonal or polyclonal, or humanized).

If applicant elects a humanized antibody, applicant is further required to elect a specific CDR (i.e. specific SEQ ID NOS).

These species are distinct because the specific antibodies differ with respect to their structures; thus each specific monoclonal or polyclonal antibody is distinct from each specific humanized antibody with respect to their structure and represents patentably distinct subject matter.

If Group V is elected, applicant is required to elect a specific nucleic acid sequence which encodes a specific antibody, or fragment thereof.

These species are distinct because the nucleic acids differ with respect to their structures; thus each specific nucleic acid sequence patentably distinct subject matter.

If Group XII is elected, applicant is required to elect a **specific** method of inhibiting IL-18 activity in a human subject suffering from a **specific** disorder (i.e. such as those recited in claim 59) comprising administering a specific type of antibody (i.e. monoclonal, polyclonal, recombinant, chimeric or humanized).

If applicant elects a humanized antibody, applicant is further required to elect a specific CDR (i.e. specific SEQ ID NOS).

These species are distinct because the methods of inhibiting IL-18 differ with respect to the specific compound administered, the steps, and the endpoint; thus each specific method employing a specific compound, or combination thereof, represents patentably distinct subject matter.

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10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

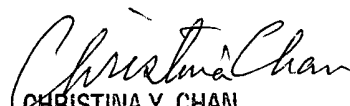
11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.  
Patent Examiner  
Technology Center 1600  
December 17, 2001

  
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SUPERVISORY PATENT EXAMINER  
GROUP 1800 / 640